



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Cincinnati Acquisition Division
26 West Martin Luther King Drive
Cincinnati, Ohio 45268

February 26, 2021

FROM: Matthew Growney, Contracting Officer

TO: Multiple Award Contract Holders under EPA ID/IQ Contract for Endocrine Disruptor Screening Program Technical and Support Services (68HE0H18D0008 & 68HE0H18D0009)

SUBJECT: Request for Task Order Proposal, Tracking Number PR-ORD-20-02465

Attached is a Request for Task Order Proposal (RFTOP) for the subject tracking number which is issued for competition for the project entitled, "Laboratory Support for Repeated Dose Oral Toxicity Studies of Poly- and Perfluoroalkyl Substances in Rats."

The Government requests the submission of a proposal, in accordance with instructions provided herein, for the task order. Submission of proposals is requested by 1600 EDT on March 15th, 2021. All applicable contract-level clauses and provisions apply.

Award of a hybrid type task order with both Firm Fixed Price and Time & Materials line items will result. The period of performance for the resultant task order will be 36 months from the date of award. Please see attached technical evaluation criteria which will be used to evaluate proposals.

Award is intended to be made without discussions. Negotiations will be conducted only if determined necessary.

All questions should be directed to the Contract Specialist, Sean Gifford, via email at Gifford.Sean@epa.gov within seven (7) calendar days of issuance of this RFTOP.

Attachments:

- Attachment 1 – Request for Task Order Proposal
 - o Performance Work Statement
 - o Task Order Clauses & Provisions
 - o Proposal Instructions
- Attachment 2 – Technical Evaluation Factors
- Attachment 3 – Past Performance Questionnaire
- Attachment 4 – Task Order QASP



ENVIRONMENTAL PROTECTION AGENCY

EPA Office of Research and Development: Laboratory Support for Repeated Dose Oral Toxicity Studies of Poly- and Perfluoroalkyl Substances in Rats

Request for Task Order Proposal (RFTOP)

1 PERFORMANCE WORK STATEMENT (PWS)

1.1 PURPOSE

The purpose of this task order (TO), *EPA Office of Research and Development: Laboratory Support for Repeated Dose Oral Toxicity Studies of Perfluoroalkyl Substances (PFAS) in Rats*, is to obtain laboratory support for the Office of Science Coordination and Policy (OSCP), Office of Chemical Safety & Pollution Prevention (OCSPP) and Office of Research and Development in four (4) general areas:

1. Determine purity, and solubility and stability of selected PFAS chemicals in dosing solution
2. Tolerability and 14-day oral dose range finding study of selected PFAS chemicals
3. 90-day oral subchronic toxicity study of selected PFAS chemicals
4. 28-day Immunotoxicity Study for Perfluoroalkyl Substances

The work under this task order falls within scope of the contract level statement of work under Section 3.1 Laboratory Testing using EPA or OECD Test Guidelines (Task 1), specifically, 3.1.2 Tier 1 and Tier 2 in vivo mammalian guideline tests (see in vivo assays in Tables 1).

Animal Care

1. Animal Welfare Oversight: Vertebrate animal studies shall be conducted by a PHS Assured and AAALAC, Int. Accredited institution using an Institutional Care and Use Committee (IACUC) approved protocol. The ownership and welfare of the animals shall be the responsibility of this Assured and Accredited institution. Assurance number and Accreditation Unit shall be provided to the EPA.
2. Animal Husbandry will follow the requirements of the Guide for the Care and Use of Laboratory Animals. Animals shall be socially housed 2 per cage. The temperature in the experimental animal room shall be 22°C (\pm 3°C) with a relative humidity of 50 \pm 20 percent. Lighting shall be artificial with a sequence of 12 hours light, 12 hours dark. Diet and water shall be provided ad libitum.

1.2 BACKGROUND

The Office of Research and Development (ORD) provides scientific research data to inform EPA's regulatory decisions and support its partners and stakeholders including the EPA Regional offices, State Environmental and Public Health programs and tribal organizations.

Per/polyfluoroalkyl substances (PFAS) are used in industrial processes and found in commercial products. Through their manufacture, use and disposal, these compounds have become anthropogenic contaminants in air, soil and water. These chemicals tend to be bioaccumulative and persistent in the environment. Several of these compounds, of which there may be thousands, have been detected in human blood. Some PFAS compounds are associated with chronic effects such as immunotoxicity and potentially cancer. ORD's Center for Computational Toxicology and Exposure (CCTE) is currently conducting high-throughput in vitro toxicity assays with many of these PFAS chemicals. However, for many of the PFAS compounds, the available data on the potential in vivo toxic effects from acute and chronic exposure are scant. In order to provide an in vivo anchor for the in vitro toxicity assay results and read-across approaches being developed, CCTE is requesting proposals to conduct repeated oral dose toxicity assays on a limited number of chemicals. The oral route was chosen as this is anticipated to be the major route of exposure for the general population, either through contaminated drinking water or food. The overall objective of this task order is to evaluate the 90-day oral toxicity of selected PFAS

compounds in the rat. To achieve this objective, the contractor shall: 1) determine the purity of EPA-selected PFAS compounds and their solubility and stability in vehicle; 2) conduct tolerability and 14-day oral dose range finding studies; 3) conduct 90-day oral toxicity studies; and 4) report the findings to the EPA. Studies may be conducted on up to six compounds. Preferably, the studies shall be conducted in parallel. For each chemical, an option to perform an additional 28-day oral immunotoxicity study may be requested.

1.3 TASK 1: TASK ORDER MANAGEMENT AND REPORTING REQUIREMENTS

Task 1 will be Time & Materials

- 1.3.1 The Contractor shall schedule a kick-off meeting/conference call with the TOCOR within 10 business days following the TO award. The TOCOR, Alternate (Alt) TOCOR, contract-level COR, and the EPA Contracting Officer (CO) must be invited to the kick-off meeting. Additional participants may be included.
- 1.3.2 The Contractor shall manage all aspects of the task order including, but not limited to, the technical, quality assurance, schedule, cost, and communication requirements.
- 1.3.3 General status meetings shall be conducted on an as needed basis and may be initiated by the TOCOR or contractor. Meetings may be required at the end of each deliverable to discuss the deliverable, progress of the overall project, problems encountered and next steps. Meetings may be held in-person or via teleconference technology such as Skype, MS Teams, Adobe Connect, etc. It is expected that much of the day-to-day communication for this task order will be conducted via email.
- 1.3.4 The Contractor shall update the TOCOR via telephone and, in writing, via e-mail, of any issues on an ongoing basis.
- 1.3.5 The Contractor shall immediately inform the TOCOR when any hours or costs for time and material contractual tasks (Task 3) that has exceeded or is expected to exceed the contractor estimate by >10%. This is for the procurement of chemicals and analytical chemistry (Task 3). Tasks 4, 5 and 6 are firm-fixed price.
- 1.3.6 The Contractor shall immediately inform the TOCOR of any problems that may impact the production, budget, and/or delivery of deliverables.
- 1.3.7 The Contractor shall notify the TOCOR when 75% of the Government approved hours or approved LH (labor hour) costs have been incurred (including unbilled hours and costs).

1.3.8 The Contractor shall provide a monthly progress report of the combined monthly technical and financial progress report) stating the progress made, including the percentage of the project completed, a description of the work accomplished to support the cost, the estimated percentage of task completed (including deliverables) during the reporting period. The Executive Summary shall summarize the planned and actual work for the month, financial status, work planned for the next month, and significant issues, risks, or concerns. The monthly report shall also provide cost and technical progress data for each time and materials task and projected costs for the upcoming reporting period.

1.3.9 **For the technical progress report also include the following specific information:**

- Narrative detail review of accomplishments during the reporting period and/or significant events, as well as an assessment of work being completed on schedule and budget.
- Status of all ongoing activities in accordance with the technical proposal and technical directives.
- List of deliverables with delivery dates (planned versus actual).
- Anticipated activities and deliverables for the next reporting period.
- Specific discussions shall include difficulties encountered and remedial action taken during the reporting period, and anticipated activity with a schedule of deliverables for the subsequent reporting period.
- List of current contractors / staffing roster and any changes that may impact deliverables in advance of the reporting period (e.g., change in personnel and vacations).
- Monthly Contractor performance information (performance metrics)

1.3.10 **For the financial report with regard to Task 3, include the following information:**

- Identification of cost issues or concerns.
- For the current period, display the amount claimed.
- For the cumulative period display the total amount claimed; amount paid; amount suspended or disallowed; and remaining amount.
- Labor hours
 - A list of employees, their labor categories, and the number of hours worked for the reporting period.
 - For the current reporting period display the expended direct labor hours (by EPA contract labor category), and the total loaded direct labor hours.

- For the cumulative reporting period and the cumulative contract period display: The negotiated and expended direct labor hours (by EPA labor hour category) and the loaded direct labor rate.
- Display the estimated direct labor hours and costs to be expended during the next reporting period.
- Display the estimates of remaining direct labor hours and costs required to complete the task order.
- Unbilled allowable costs. Display the total costs incurred but unbilled for the current reporting period and cumulative for the task order.
- Average total cost labor hour. For the current contract period, compare the actual total cost per hour to date with the average total cost per hour of the approved technical proposal for the task order.
- The monthly report does not change the notification requirements of the “Limitation of Cost” or “Limitation of Funds” clauses requiring separate written notice to the Contracting Officer.

1.3.11 The Contractor shall maintain a cumulative record of all communications between the contractor and EPA (all media including e-mail and telephone calls) and provide it to the TOCOR within one month after the TO has ended.

1.3.12 The contractor shall provide all deliverables in an electronic format specified by the EPA TOCOR (e.g., Word, Excel, Access, HTML) via electronic mail. The Contractor shall format any deliverables intended for posting on an EPA public website to comply with Section 508.

1.3.13 Unless otherwise specified by the TOCOR, the Contractor shall provide a secure method for internet transfer of large files.

1.3.14 All deliverables for this task order are the property of EPA.

1.3.15 Contractor personnel shall identify themselves as contractor employees and shall not present themselves as EPA employees. Furthermore, they shall not represent view of the U.S. Government, EPA, or its employees. In addition, the contractor shall not engage in inherently governmental activities, including, but not limited to actual determination of EPA policy and preparation of documents on EPA letterhead other than routine correspondences.

1.4 **TASK 2: QUALITY ASSURANCE AND QUALITY ASSURANCE PROJECT PLAN (QAPP)**

The Contractor shall implement a quality system that meets ANSI standard E4-2014.

Task 2 will be Firm-Fixed Price.

For planning purposes, assume that a Quality Assurance Project Plan (QAPP) will be required for Tasks 3, 4 and 5. The contractor shall create a Quality Assurance Project Plan (QAPP) that documents

the planning, implementation, and assessment procedures for quality assurance and quality control activities. The QAPP integrates all the technical and quality aspects of the project to provide a blueprint for obtaining the type and quality of data and information needed for a specific decision or use. The QAPP shall be prepared in accordance with the specifications identified by EPA (found at <https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans>).

- Within 10 business days after Task Order Award, the contractor shall prepare and submit for EPA review a draft Quality Assurance Project Plan (QAPP) for Tasks 3, 4 and 5. The QAPP shall be submitted to the TO COR.
- EPA will review the contractor’s draft QAPP and provide the Contractor with written approval or written comments.
- If needed, the Contractor shall submit a revised QAPP within 5 business days of receipt of the written comments on the draft QAPP, unless otherwise instructed by the EPA TO COR.
- Under no circumstances shall work that involves the generation, collection, evaluation, analysis, or use of environmental data be performed by the contractor until the contractor receives written notification from the EPA TO COR that EPA has approved the contractor’s QAPP.
- All QA documentation, including the QAPP, prepared under this Task Order, shall be considered non-proprietary, and shall be made available to the public upon request.
- The contractor also shall provide EPA with monthly reports of QA-related activities performed during implementation of this Task Order. These monthly QA reports shall identify QA activities performed to support implementation of this task order, problems encountered, deviations from the QAPP, and corrective actions taken.

1.5 TASK 3: CHEMICAL PROCUREMENT AND ANALYTICAL CHEMISTRY

Purpose: The purpose of Task 3 is for the contractor to purchase selected PFAS chemicals and to develop analytical chemistry methods to determine the purity, and solubility and stability of the PFAS chemicals in dosing vehicle.

Task 3 will be Time and Materials

Task 3.1: Chemical Procurement

The following chemicals shall be used in the study:

DTXSID	Name	CAS RN
DTXSID00194615	1H,1H,9H-Perfluorononyl acrylate	4180-26-1
DTXSID1047578	1H,1H,2H,2H-Perfluorohexyl iodide	2043-55-2
DTXSID9059834	Perfluamine	338-83-0
DTXSID00188993	Methyl heptafluoropropylketone	355-17-9
DTXSID 3031860	Nonadecafluorodecanoic acid	335-76-2

A. Chemical Procurement

The contractor shall purchase the chemical(s) selected by the EPA. Preferably, a single lot shall be used throughout the study.

B. Deliverables

Provide the EPA information regarding test chemical procured. Include purity (manufacturer), lot number, and other information provided by the manufacturer. Information provided electronically in Word format. Report shall be submitted within two weeks of acquisition of chemical.

Task 3.2: Chemical Purity

A. Chemical Purity

The contractor shall develop analytical methods (LC-MS/MS or GC-MS/MS, based on EPA recommendations) to determine the purity of the purchased chemicals. If multiple lots of the chemical are purchased, purity checks on each lot are required. The contractor must generate Standard Operating Procedures (SOPs) for the analytical chemistry methods. Purity of test chemicals shall be >95%, unless specifically approved by EPA. The levels of the potential contaminants perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) shall be reported.

Task 3.3: Chemical Solubility and Stability

A. Solubility and stability of chemical in vehicle

The contractor shall determine the solubility and stability of the test compounds in appropriate vehicle using chromatographic/mass spectrometry methods. A standard set of dosing vehicles shall be evaluated for chemical solubility and stability. The vehicles may include deionized water, 1:1:8 Kolliphor:ethanol:deionized water, and deionized water with 20% Tween® 80. The solubility and stability of the chemicals in other vehicles may be assessed as needed. The stability of the chemical shall be evaluated in the dosing solution for 7 days. The dosing vehicle used in the study shall be approved by the US EPA. In some cases, chemical may be used in suspension. Deviation of concentration of test chemical in dosing solutions greater than 10% from target concentration are considered out of tolerance.

B. Deliverables

Within two (2) months of the approval of the QAPP a draft of all SOPs shall be provided to the EPA for approval. Each SOP shall have clearly labeled sections similar to: 1.0 Purpose; 2.0 Scope; 3.0 Responsibilities; 4.0 Procedures; 5.0 References. The draft SOPs shall be delivered to the EPA electronically in MS Word format and all data shall be provided in Excel spreadsheets. The EPA reserves the right to review or modify the SOPs prior to approval. SOPs must be approved before task order work can move forward into Task 4.

Within 3 months of the approval of the QAPP, a draft analytical chemistry report shall be provided to the EPA for each test chemical. Each analytical chemistry report shall include the

detailed analytical method, the Limit of Quantitation (LOQ) and Level of Detection (LOD), the purity of the test chemical, and the solubility and stability of the test chemical in the dosing vehicle. This analytical chemistry report shall be in a Word format with all data provided in an Excel format and must be approved by EPA before any in vivo testing (Task 4.1) shall occur. In the event that a chemical does not pass purity or stability checks, the EPA shall provide an alternative chemical.

1.6 TASK 4: ORAL TOXICITY STUDY – DOSE RANGE FINDING

Purpose: The purpose of Task 4 is for the contractor to conduct a phased non-GLP an acute oral tolerability study and a 14-day repeated dose oral toxicity study to determine doses that shall be used in the 90-day study.

Studies may be conducted on up to 6 compounds.

Task 4 will be Firm-Fixed Price

Task 4.1: Tolerability Study

A. Tolerability Study

The contractor shall conduct a non-GLP tolerability study for each chemical to be evaluated in the subchronic study. The purpose of the tolerability study is to guide dose selection for the 14-day dose range finding study. Up to six (6) tolerability studies may be conducted depending on funding. The study design is as follows:

- 1) Species and Sex: Testing shall be performed in male Sprague-Dawley IGS rats from Charles Rivers Laboratory.
- 2) Age: Testing shall be performed with clinically healthy animals following a 7 – 10-day acclimation period. Dosing shall begin with animals no later than 8 – 9 weeks of age.
- 3) Weight: at the commencement of the study the weight variation of animals used shall be within 20 percent of the mean weight for each sex.
- 4) Numbers: A total of 3 animals shall be used per dose level.
- 5) Animal Husbandry: Studies shall be conducted in a facility accredited by the Association for the Assessment and Accreditation for Laboratory Animal Laboratory Care (AAALAC). Animals shall be group housed 2 per cage. The temperature in the experimental animal room shall be 22°C (\pm 3°C) with a relative humidity of 50 \pm 20 percent. Lighting shall be artificial with a sequence of 12 hours light, 12 hours dark. Diet and water shall be provided ad libitum.
- 6) Control and Test Substance: The vehicle and test substances will be defined in Task 3.
- 7) Dose Levels: A total of 4 dose levels shall be used. Dose levels will be provided by EPA. A concurrent vehicle control group is required.
- 8) Administration of Test Substance: The test substance shall be administered as a single dose, oral gavage, 5 ml/kg.

9) Observation Period and Observations: The animals shall be observed for 72 hours following dosing. Observations shall be made at least twice each day for morbidity and mortality. General clinical observations shall be made at least twice a day, preferably at the same time each day. Effort shall be made to ensure that variations in the observation conditions are minimal. Observations shall be detailed and carefully recorded, preferably using scoring systems, explicitly defined by the testing laboratory. Signs noted shall include, but not be limited to, changes in skin, fur, eyes, mucous membranes, occurrence of secretions and excretions and autonomic activity (e.g., lacrimation, piloerection, pupil size, unusual respiratory pattern). Changes in gait, posture and response to handling as well as the presence of clonic or tonic movements, stereotypies (e.g., excessive grooming, repetitive circling) or bizarre behavior (e.g., self-mutilation, walking backwards) shall be recorded. Measurement of food and water consumption shall be recorded over the 72-hour period. Individual weights of animals shall be determined shortly before the test substance is administered and at death or scheduled sacrifice. Moribund animals shall be removed and sacrificed when noticed and the time of death shall be recorded as precisely as possible. At termination, all survivors in the treatment and control groups shall be sacrificed.

10) Data and Reporting: Data shall be summarized in tabular form, showing for each test group the number of animals at the start of the test, the number of animals showing lesions, the types of lesions and the percentage of animals displaying each type of lesion. In addition to reporting requirements, the following specific information shall be reported:

a. Test substance characterization shall include:

i. Chemical identification.

ii. Lot or batch number.

iii. Physical properties.

iv. Purity/impurities.

v. Identification and composition of any vehicle used.

b. Test system shall contain data on:

i. Species and strain of animals used.

ii. Age including body weight data and sex.

iii. Test environment including cage conditions, ambient temperature, humidity, and light/dark periods.

iv. Identification of animal diet.

v. Acclimation period.

- c. Test procedure shall include the following data:
 - i. Method of randomization used.
 - ii. Full description of experimental design and procedure.
 - iii. Dose regimen including levels, methods, and volume.
- d. Test results shall include:
 - i. Group animal data. Tabulation of toxic response data by sex and exposure level for:
 - 1. Number of animals exposed.
 - 2. Number of animals showing signs of toxicity.
 - 3. Number of animals dying.
 - ii. Individual animal data. Data shall be presented as summary (group mean) as well as for individual animals.
 - 1. Date of death during the study or whether animals survived to termination.
 - 2. Date of observation of each abnormal sign and its subsequent course.
 - 3. Body weight data.
 - 4. Feed and water (if collected) consumption data.
 - 5. Dose (mg/kg/day).
 - 6. Statistical treatment of results, where appropriate.

B. Deliverables

Within two (2) weeks of completion of the tolerability study (Task 4.1), the contractor shall provide a report of the study results electronically to the EPA in MS Word format and all data in Excel spreadsheets.

Task 4.2: Dose Range Finding Study

A. 14-Day Repeated Oral Dose Range Finding Study

The contractor shall conduct a non-GLP, 14-day repeated oral dose range finding study for each chemical evaluated in a subchronic toxicity study. The purpose of the dose range finding study is to guide dose selection for the subchronic toxicity study. Up to six (6) 14-day dose range studies may be conducted depending on funding. The study design is as follows:

- 1) Species and Sex: Testing shall be performed in male and female Sprague-Dawley IGS rats from Charles Rivers Laboratory.

- 2) Age: Testing shall be performed with clinically healthy animals following a 7 – 10-day acclimation period. Dosing shall begin with animals no later than 8 – 9 weeks of age.
- 3) Weight: at the commencement of the study the weight variation of animals used shall be within 20 percent of the mean weight for each sex.
- 4) Numbers: A total of 5 animals per sex per dose level shall be used.
- 5) Animal Husbandry: Studies shall be conducted in a facility accredited by the Association for the Assessment and Accreditation for Laboratory Animal Laboratory Care (AAALAC). Animals shall be group housed 2 per cage. The temperature in the experimental animal room shall be 22°C (\pm 3°C) with a relative humidity of 50 \pm 20 percent. Lighting shall be artificial with a sequence of 12 hours light, 12 hours dark. Diet and water shall be provided ad libitum.
- 6) Control and Test Substance: The vehicle and test substances shall be defined in Task 3.
- 7) Dose Levels: A total of 3 dose levels shall be used. Dose levels shall be provided by EPA based on the tolerability study. The high dose shall demonstrate adverse, but survivable effects, preferably in the high-dose group only. A concurrent vehicle control group is required.
- 8) Administration of Test Substance: The test substance shall be administered via oral gavage (5 ml/kg) every day for 14 consecutive days. The dose shall be given at approximately the same time each day and adjusted based on daily body weights to maintain a consistent dose level.
- 9) Observation Period and Observations: The animals shall be observed for 14 days. Observations shall be made at least twice each day for morbidity and mortality. Appropriate actions shall be taken to minimize loss of animals to the study (e.g., necropsy or refrigeration of those animals found dead and isolation or sacrifice of weak or moribund animals). General clinical observations shall be made at least once per day, preferably at the same time each day. Effort shall be made to ensure that variations in the observation conditions are minimal. Observations shall be detailed and carefully recorded, preferably using scoring systems, explicitly defined by the testing laboratory. Signs noted shall include, but not be limited to, changes in skin, fur, eyes, mucous membranes, occurrence of secretions and excretions and autonomic activity (e.g., lacrimation, piloerection, pupil size, unusual respiratory pattern). Changes in gait, posture and response to handling as well as the presence of clonic or tonic movements, stereotypies (e.g., excessive grooming, repetitive circling) or bizarre behavior (e.g., self-mutilation, walking backwards) shall be recorded. Measurement of food consumption shall be recorded weekly. Individual weights of animals shall be determined each day before the test substance is administered and at death. Moribund animals shall be removed and sacrificed when noticed and the time of death shall be recorded as precisely as possible.
- 10) Sacrifice: At termination, all survivors in the treatment and control groups shall be weighed and then sacrificed. The order of sacrifice among animals shall be randomized.

- 11) Clinical Pathology: Hematology and clinical chemistry examinations shall be made on all animals, including controls, of each sex in each group. The hematology and clinical chemistry parameters shall be examined at terminal sacrifice at the end of the study. Overnight fasting of the animals prior to blood sampling is recommended.
- a. Hematology. Measured endpoints shall be red blood cell count, hemoglobin concentration, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, and mean corpuscular hemoglobin concentration, white blood cell count, differential leukocyte count, platelet count, and a measure of clotting potential, such as prothrombin time or activated partial thromboplastin time.
 - b. Clinical chemistry. Measured endpoints shall be potassium, sodium, glucose, total cholesterol, urea nitrogen, creatinine, total protein and albumin. Hepatic enzymes alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase shall also be measured.
- 12) Toxicokinetics: On the first day of dosing, blood shall be collected (using K3 EDTA as anticoagulant) from the retro-orbital plexus under 70% CO₂:30% O₂ anesthesia. plasma shall be isolated, stored at -80° C (2 x 50 µL aliquots of each). The first blood collection shall be done at approximately 2 hours post-administration. The time of collection shall be recorded. At the time of sacrifice, blood shall be collected (using K3 EDTA as anticoagulant) by cardiac puncture under 70% CO₂:30% O₂ anesthesia. Plasma shall be isolated, stored at -80° C (6 x 100 µL aliquots of each). The time of blood collection and necropsy shall be recorded for all animals. Plasma samples analyzed by contractor for parent compound and metabolites by a suitable chromatographic/mass spectrometry method.
- 13) Ophthalmological Examination: Ophthalmological examinations using an ophthalmoscope or an equivalent device shall be made on all animals prior to the administration of the test substance and on all high dose and control groups at termination. If changes in the eyes are detected, all animals in the other dose groups shall be examined.
- 14) Gross Necropsy: All animals shall be subjected to a full gross necropsy which includes examination of the external surface of the body, all orifices, and the cranial, thoracic and abdominal cavities and their contents.
- a. The liver, kidneys, lungs, adrenals, testes, epididymides, ovaries, uterus, thymus, spleen, brain, and heart shall be trimmed and weighed wet, as soon as possible after dissection.
 - b. The following organs and tissues, or representative samples thereof, shall be preserved in a suitable medium for histopathological examination:
 - i. Digestive system—salivary glands, esophagus, stomach, duodenum, jejunum, ileum, cecum, colon, rectum, liver, pancreas, gallbladder (when present).
 - ii. Nervous system—brain (including sections of medulla/pons, cerebellum and cerebrum), pituitary, peripheral nerve (sciatic or tibial, preferably in close

proximity to the muscle), spinal cord (three levels: cervical, mid-thoracic and lumbar), eyes (retina, optic nerve).

- iii. Glandular system—adrenals, parathyroid, thyroid.
- iv. Respiratory system—trachea, lungs, pharynx, larynx, nose.
- v. Cardiovascular/hemopoietic system—aorta, heart, bone marrow (and/or fresh aspirate), lymph nodes (preferably one lymph node covering the route of administration and another one distant from the route of administration to cover systemic effects), spleen, thymus.
- vi. Urogenital system—kidneys, urinary bladder, prostate, testes, epididymides, seminal vesicle(s), uterus, ovaries, female mammary gland.
- vii. Others—all gross lesions and masses, skin.

15) Histopathology: The following histopathology shall be performed:

- a. Full histopathology on the organs and tissues listed under 15(b) of all animals in the control and high dose groups. If changes in an organ or tissue are detected, all animals in the other dose groups shall be examined. If excessive early deaths or other problems occur in the high dose group compromising the significance of the data, the next dose level shall be examined for complete histopathology.
- b. Full histopathology shall be performed on the organs and tissues listed under 15(b) in all animals that died or were killed during the study.
- c. Full histopathology shall be performed on all gross lesions in all animals.
- d. An attempt shall be made to correlate gross observations with microscopic findings.
- e. Tissues and organs designated for microscopic examination shall be fixed in 10 percent buffered formalin or a recognized suitable fixative as soon as necropsy is performed and no less than 48 hours prior to trimming.

16) Data and Reporting: Data shall be summarized in tabular form, showing for each test group the number of animals at the start of the test, the number of animals showing lesions, the types of lesions and the percentage of animals displaying each type of lesion. In addition to reporting requirements, the following specific information shall be reported:

- a. Test substance characterization shall include:
 - i. Chemical identification.
 - ii. Lot or batch number.
 - iii. Physical properties.
 - iv. Purity/impurities.
 - v. Identification and composition of any vehicle used.

- b. Test system shall contain data on:
 - i. Species and strain of animals used.
 - ii. Age including body weight data and sex.
 - iii. Test environment including cage conditions, ambient temperature, humidity, and light/dark periods.
 - iv. Identification of animal diet.
 - v. Acclimation period.

- c. Test procedure shall include the following data:
 - i. Method of randomization used.
 - ii. Full description of experimental design and procedure.
 - iii. Dose regimen including levels, methods, and volume.

- d. Test results shall include:
 - i. Group animal data. Tabulation of toxic response data by sex and exposure level for:
 - 1. Number of animals exposed.
 - 2. Number of animals showing signs of toxicity.
 - 3. Number of animals dying.

 - ii. Individual animal data. Data shall be presented as summary (group mean) as well as for individual animals.
 - 1. Date of death during the study or whether animals survived to termination.
 - 2. Date of observation of each abnormal sign and its subsequent course.
 - 3. Body weight data.
 - 4. Feed and water (if collected) consumption data.
 - 5. Dose (mg/kg/day).
 - 6. Results of toxicokinetic evaluation.
 - 7. Results of ophthalmological examination.
 - 8. Results of hematological tests performed.
 - 9. Results of clinical chemistry tests performed.
 - 10. Results of urinalysis, if performed.
 - 11. Necropsy findings, including absolute and relative (to body weight) organ weight data.
 - 12. Detailed description of all histopathological findings.
 - 13. Statistical treatment of results, where appropriate.

B. Deliverables

Within 11 weeks following necropsy in the 14-day repeated oral dose range finding study (Task 4.2), the contractor shall provide a report of the study results electronically to the EPA in MS Word format and all data in Excel spreadsheets.

1.7 TASK 5: REPEATED DOSE 90-DAY ORAL TOXICITY STUDY

Purpose: The purpose of Task 5 is for the contractor to conduct a GLP-compliant, repeated dose 90-day oral toxicity study in the rat. The contractor shall follow the EPA Health Effects Test Guideline OPPTS 870.3100 “90–Day Oral Toxicity in Rodents” with modifications listed below in Section 5.1A. Studies may be conducted on up to six compounds.

Task 5 will be Firm Fixed Price.

Task 5.1: Repeated Dose 90-Day Oral Toxicity Study

A. Repeated Dose 90-Day Oral Toxicity Study

Modifications to the study design:

- 1) Species and Sex: Testing shall be performed in male and female Sprague-Dawley IGS rats from Charles Rivers Laboratory.
- 2) Control and Test Substance: The vehicle and test substances will be defined in Task 3.
- 3) Dose Levels: A total of 5 dose levels shall be used. Dose levels will be provided by USEPA based on the 14-day oral dose range finding study. The highest dose level shall result in toxic effects but not produce an incidence of fatalities which would prevent a meaningful evaluation. The intermediate dose levels shall be spaced to produce a gradation of toxic effects. The lowest dose level shall produce no evidence of toxicity. A concurrent vehicle control group is required.
- 4) Administration of Test Substance: The test substance shall be administered via oral gavage (5 ml/kg) every day for 90 consecutive days. The dose shall be given at approximately the same time each day and adjusted based on weekly body weights to maintain a consistent dose level.
- 5) Sacrifice: At termination, all survivors in the treatment and control groups shall be weighed and then sacrificed. The order of sacrifice among animals shall be randomized.
- 6) Gross Necropsy: All animals shall be subjected to a full gross necropsy which includes examination of the external surface of the body, all orifices, and the cranial, thoracic and abdominal cavities and their contents.
 - a. The liver, kidneys, lungs, adrenals, testes, epididymides, ovaries, uterus, thymus, spleen, brain, and heart shall be trimmed and weighed wet, as soon as possible after dissection.

B. Deliverables

Within 4 months of the necropsy in the subchronic study, the contractor shall provide a report of the study results electronically to the EPA in MS Word format and all data in Excel spreadsheets.

Task 5.2: Collect, Compile, Review Data and Prepare, Submit Reports

When all tasks for each test chemical have been completed or at the end of the POP, the contractor shall compile the data into one (1) electronic document. The written report, in MS Word, shall include analytical chemistry results of the stock, methods and results of the toxicity assays and analytical chemistry methods, and a section detailing any deviations or observed anomalies. The report must describe the methods and findings and shall include a comparison of test data to any control data with a description of significant findings.

QC shall be conducted on actual calculated numbers and not solely on data recording sheets. If problems are found in 10% of data that initially undergo a random check in accordance with the QC process, the remaining 90% of data shall be reviewed.

The data shall be provided to the TO COR electronically in an MS Excel spreadsheet or other similar electronic format. The data sheets shall be delivered to the TO COR after review by a/the senior scientist for data soundness and scientific relevance. All data shall be submitted (suspected outliers shall not be omitted from the report to EPA). The contractor shall ensure the overall quality of the final reports.

The draft report and data shall be delivered to the TO COR after review by the contractor senior scientist and the contractor Quality Assurance Manager (QAM) for scientific relevance and data soundness, respectively. These deliverables shall be as complete as possible and free of typographical errors and shall be provided as a cohesive unit that encompasses all assays performed for a specific chemical.

1.8 TASK 6 (OPTIONAL): REPEATED DOSE 28-DAY ORAL IMMUNOTOXICITY STUDY IN RATS

Purpose: The purpose of Task 6 is for the contractor to conduct a GLP-compliant repeated dose 28-day oral immunotoxicity study in rats. Contractor work on this task is dependent on the availability of funds. The contractor shall use the technical guidelines as described in the EPA Health Effects Guideline OPPTS 860.7800 Immunotoxicity with modifications as described in Section 6.3(A).

Task 6 will be Firm-Fixed Price

Task 6.1: Provide Revised Quality Assurance Project Plan and Standard Operating Procedures for 28-day oral immunotoxicity study

The Contractor shall implement a quality system that meets ANSI standard E4-2014.

For planning purposes, assume that a Quality Assurance Project Plan (QAPP) will be required for Task 6. The contractor shall create a revised Quality Assurance Project Plan (QAPP) that documents the planning, implementation, and assessment procedures for quality assurance and quality control activities. The QAPP integrates all the technical and quality aspects of the project to provide a blueprint for obtaining the type and quality of environmental data and information needed for a specific decision or use. The QAPP shall be prepared in accordance with the specifications identified by EPA (found at <https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans>).

- Within 10 business days after technical direction to begin optional Task 6, the contractor shall revise the QAPP and submit the revised QAPP to the TO COR for review.
- EPA will review the contractor's draft revised QAPP and provide the Contractor with written approval or written comments.
- If needed, the Contractor shall submit a revised QAPP within 5 business days of receipt of the written comments on the draft QAPP, unless otherwise instructed by the EPA TO COR.
- Under no circumstances shall work that involves the generation, collection, evaluation, analysis, or use of environmental data be performed by the contractor until the contractor receives written notification from the EPA TO COR that EPA has approved the contractor's QAPP.

- All QA documentation, including the QAPP, prepared under this Task Order, shall be considered non-proprietary, and shall be made available to the public upon request.
- The contractor also shall provide EPA with monthly reports of QA-related activities performed during implementation of this Task Order. These monthly QA reports shall identify QA activities performed to support implementation of this task order, problems encountered, deviations from the QAPP, and corrective actions taken.
- Within 2 months of acceptance of QAPP, provide draft SOPs for Task 6.2 and 6.3.

Task 6.2: Determine optimum dose of sheep red blood cells administered and time to collect to collect sera.

A. Immunization with sheep red blood cells

- 1) Sheep red blood cells are used to immunize the rats in this study. Before conducting the main study, the optimum dose of sheep red blood cells and the time to collect blood from the immunized rats needs to be determined. Male and female Sprague-Dawley IGS rats from Charles Rivers Laboratory, 3 animals /sex/dose, aged 10-12 weeks shall be used in this study. Three concentrations and three time points shall be used and determined after consultation between the contractor and EPA. The animals must be immunized by intravenous injection of sheep red blood cells. Control animals shall be treated with vehicle. The animals shall be monitored once per day for signs of any side effects from administration of the red blood cells. Moribund animals shall be euthanized. The animals shall be euthanized on either 4, 5 or 6 days after administration of SRBC. Blood and spleen shall be collected. Spleen cells shall be isolated or serum shall be prepared and, either the plaque forming cell (PFC) assay (measures IgM response) or an enzyme linked immunosorbent assay (ELISA) (measures IgM levels) must be performed, respectively, to determine the optimum concentration of SRBCs and sacrifice time for the immunotoxicology study. See Temple et al. (1993, 1995) for more details in References below. Decision on the assay shall be made in consultation with EPA.
- 2) Report of results shall include:
 - a. Test substance characterization
 - i. Source of sheep red blood cells and lot number if available.
 - b. Test system
 - i. Source of animals with age, weight and sex
 - ii. Animal husbandry conditions
 - iii. Diet
 - c. Experimental procedure
 - i. Method of randomization of animals
 - ii. Full description of experimental design and procedure
 - iii. Dose regimen
 - d. Test results
 - i. Group animal data
 1. Number of animals exposed

2. Number of animals displaying adverse effect
 - a) Description of the adverse effects
3. Number of animals dying
4. Results of IgM response or concentration, depending on the test conducted.

B. Deliverable

Within one month of completion of study, the contractor shall provide a report of the study results electronically to the EPA in MS Word format and all data in Excel spreadsheets.

Task 6.3: Repeated Dose 28-day Oral Immunotoxicity Study.

A. Oral Dose Immunotoxicity Study

Modifications to the study design:

- 1) Species and Sex: Testing shall be performed in Sprague-Dawley IGS rats from Charles Rivers Laboratory. The sex of the animals used in the study will be selected by EPA.
- 2) Control and Test Substance: The vehicle and test substances will be defined in Task 3.
- 3) Dose Levels: A total of 5 dose levels shall be used. Dose levels will be provided by USEPA based either on the 14-day oral dose range finding study or the 90-day oral toxicity study. The highest dose shall not produce significant stress, malnutrition or fatalities, but produce some sign of measurable general toxicity (e.g., ten percent loss of body weight). A concurrent vehicle control group and positive control (cyclophosphamide) are required.
- 4) Administration of Test Substance: The test substance shall be administered via oral gavage (5 ml/kg) every day for 28 consecutive days. The dose shall be given at approximately the same time each day and adjusted based on weekly body weights to maintain a consistent dose level.

B. Deliverables

Within 4 months of necropsy in the immunotoxicity study, the contractor shall provide a report of the study results electronically to the EPA in MS Word format and all data in Excel spreadsheets.

1.9 REPORTING REQUIREMENTS AND DELIVERABLES

The contractor shall provide the following deliverables listed in Table 2.

Table 1 Deliverables and Schedule

Tasks	Deliverables	Due Dates
Task 1	Task management ✓ Kick-off meeting within 2 weeks after the task order has been awarded. ✓ Monthly Progress Report (i.e. Technical/Progress Status Report and Financial Status Report) by the 15 th of each month (following completion of 1 st reporting period). ✓ Biweekly status meetings ✓ Other meetings as required by the TOCOR ✓ Email a copy of Monthly Progress Report to the CO, Contract level COR, TOCOR, and Alt TOCOR	

Tasks	Deliverables	Due Dates
	<ul style="list-style-type: none"> ✓ Immediately inform the TOCOR when any hours or costs for any task has exceeded or is expected to exceed the contractor estimate by >10%. ✓ Immediately inform the TOCOR of any problems that may impact the production, budget, and/or delivery of deliverables. ✓ The Contractor shall notify the TOCOR when 75% of the Government approved hours or approved LH costs have been incurred (including unbilled hours and costs). 	
Task 2	<p>EPA Requirements for Quality Assurance Project Plans (QA/R- 5) https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans</p> <ul style="list-style-type: none"> ✓ Draft QAPP ✓ Final QAPP 	<ul style="list-style-type: none"> ✓ Draft QAPP. Within 10 business days after Task Order Award. ✓ Final QAPP. Within 5 business days of receipt of the written comments on the draft QAPP, unless otherwise instructed by the EPA TO COR.
Task 3.1	<ul style="list-style-type: none"> ✓ Provide EPA information regarding test chemical procured. Include purity, lot number, and other information provided by the manufacturer. Information provided electronically in Word format. 	<ul style="list-style-type: none"> ✓ Within two weeks of acquisition of chemical.
Task 3.3	<ul style="list-style-type: none"> ✓ Draft SOPs shall be provided to the EPA/EPA for approval. Each SOP shall have clearly labeled sections similar to: 1.0 Purpose; 2.0 Scope; 3.0 Responsibilities; 4.0 Procedures; 5.0 References. The draft SOPs shall be delivered to the EPA electronically in MS Word format and all data shall be provided in Excel spreadsheets. ✓ The analytical chemistry methods must be finalized. For each test chemical, a brief report shall be provided to the EPA which outlines the method and clearly indicates the Limit of Quantitation (LOQ) and Level of Detection (LOD) achieved with that method. Purity of test chemicals shall be reported and must >95%. The levels of the potential contaminants perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid shall be reported. This report shall be in a Word format with all data provided in an Excel format 	<ul style="list-style-type: none"> ✓ Draft SOP within two (2) months approval of QAPP ✓ Chemical purity determination within three (3) months after acceptance of QAPP.

Tasks	Deliverables	Due Dates
Task 3.3	✓ Report on solubility and stability of test chemical in vehicle. Report shall include vehicles tested, methods used to measure solubility and stability, solubility, stability of the test chemical in the vehicle for 7 days. This report shall be in a Word format with all data provided in an Excel format	✓ Within three (3) months of acceptance of QAPP.
Task 4.1	✓ Report on oral tolerability study. Report shall be in MS Word format and data in Excel spreadsheet.	✓ Within two (2) weeks of completion of study. ✓
Task 4.2	✓ Report on 14-day repeated dose oral toxicity study. Report shall be in MS Word format and data in Excel spreadsheet.	✓ Within eleven (11) weeks of completion of study
Task 5.1	✓ Report on 90-day repeated dose oral toxicity study. Report shall be in MS Word format and data in Excel spreadsheet.	✓ Within four (4) months of completion of the study.
Task 6.1	✓ Draft QAPP	✓ Within 10 business days after Task Order Award.
Task 6.2	✓ Report on concentration of SRBCs to use in immunotoxicology study	✓ Within one (1) month of completion of study
Task 6.3	✓ Report of the study results electronically to the EPA in MS Word format and all data in Excel spreadsheets.	✓ Within 4 months of necropsy in the immunotoxicity study

1.10 ACCEPTABLE QUALITY LEVEL FOR TASKS

See Attachment 1: Quality Assurance Surveillance Plan

1.11 PERIOD OF PERFORMANCE

The period of performance of this task order is:

BASE: 36 months from award date.

1.12 PLACE OF PERFORMANCE

Work shall be performed off-site.

1.13 PERSONNEL

The Contractor is responsible for providing personnel with the necessary level expertise to support the task activities and requirement in this PWS.

1.14 TASK ORDER TYPE: TIME & MATERIALS AND FIRM FIXED PRICE

1.15 GOVERNMENT FURNISHED PROPERTY (GFP)

In accordance with FAR 45.102, the contractor shall furnish all property required for performing Government contracts. If a contractor believes that Government property is required for performance of the contract, the contractor shall submit a written request to the CO. For cost purposes, assume that EPA shall provide an office phone with voicemail, and e-mail for approved personnel working in OSCP-space to complete work under Task 3 of this task order.

1.16 TRAVEL

The Contractor may be required to travel in the course of the performance of this task order. The Contractor is required to follow the requirements of subpart 31.2 of the FAR regulations in incurring allowable travel costs under this task order, and correspondingly must, at all times, seek and obtain government rates whenever available and observe current subsistence ceilings.

1.17 TRAINING

EPA-H-31-105 APPROVAL OF TRAINING [see Section H.22 of the ID/IQ contract]

- (a) The contractor shall provide and maintain a qualified staff of personnel to meet the requirements of the Performance Work Statement. The contractor shall provide training to keep its personnel abreast of changes to the science and/or technology associated with the requirements of the contract. In addition, the contractor shall ensure that its personnel receive appropriate safety, health and environmental training in accordance with Federal, state and local requirements prior to assigning any task that require such training. The contractor shall provide documentation of such training upon the request of the Contract-Level COR and/or Contracting Officer.

The Government will not directly reimburse the cost for contractor employees to meet or maintain minimal contract requirements or to obtain and sustain an appropriate level of professionalism. Any direct charges for training will only be considered for reimbursement under this contract by compliance with the procedures set forth in paragraph (b) (see Section H.22 of the IDIQ contract).

2 INSPECTION AND ACCEPTANCE

QUALITY ASSURANCE PROJECT PLAN (SEE TASK 2 ABOVE)

The Contractor shall submit a draft QAPP per EPA Requirements for Quality Assurance Project Plans (QA/R-5)

Table 3. Quality Assurance Project Plan

	Documentation	Specifications	Due
X	Quality Assurance Project Plan for the Task Order	EPA Requirements for Quality Assurance Project Plans (QA/R-5) (dated 3//20/2011) https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans	<ul style="list-style-type: none"> ✓ Draft QAPP. Within 10 business days after Task Order Award. ✓ Final QAPP. Within 5 business days of receipt of the written comments on the draft QAPP, unless otherwise instructed by the EPA TO COR.

3 TASK ORDER ADMINISTRATION DATA

3.1 CONTRACT ADMINISTRATION REPRESENTATIVES

- Contracting Officer: TBD
- Contract Specialist: TBD
- Contract Level Contracting Officer’s Representative: TBD
- Task Order Contracting Officer’s Representative: TBD

3.2 TASK ORDER CLAUSES

EPAAR 1552.237-72 KEY PERSONNEL (APR 1984)

(a) The Contractor shall assign to this contract the following key personnel:

Lead Chemist: TBD

Lead Pathologist: TBD

Study Director: TDB

(b) During the first ninety (90) days of performance, the Contractor shall make no substitutions of key personnel unless the substitution is necessitated by illness, death, or termination of employment. The Contractor shall notify the Contracting Officer within 15 calendar days after the occurrence of any of these events and provide the information required by paragraph (c) of this clause. After the initial 90-day period, the Contractor shall submit the information required by paragraph (c) to the Contracting Officer at least 15 days prior to making any permanent substitutions.

(c) The Contractor shall provide a detailed explanation of the circumstances necessitating the proposed substitutions, complete resumes for the proposed substitutes, and any additional information requested by the Contracting Officer. Proposed substitutes should have comparable qualifications to those of the persons being replaced. The Contracting Officer will notify the

Contractor within 15 calendar days after receipt of all required information of the decision on substitutions. This clause will be modified to reflect any approved changes of key personnel.
(End of clause)

EPA-L-36-101 RFTOP PROPOSAL INSTRUCTIONS

The offeror's response is to be submitted via email to the Contract Specialist, Sean Gifford, at Gifford.Sean@epa.gov in two volumes (Technical and Price). The technical proposal is to be separate from the price proposal. **Offerors' proposals submitted via any other means without prior written approval of the Contracting Officer WILL NOT be evaluated.**

Responses are subject to the following requirements and limitations:

The maximum length of the technical portion of the proposal shall be no longer than 15 pages. This page limitation does not apply to a cover letter, tabs/section separators, resumes, charts, figures, or other illustrations. A "page" consists of a single-side of text, printed on 8 ½" x 11" paper. The technical proposal shall be submitted on 8 ½" x 11" size pages, printed double-sided, using no less than eleven (11) point character size, and no less than an average of 1" margins around each page. Offerors shall use Times New Roman font. Tables shall use no smaller than ten (10) point character size and must be clear and readable. Figures, diagrams, and charts (such as organizational charts) shall use no smaller than eight (8) point character size. Offerors are required to adhere to all of the aforementioned page limitations and instructions. Information found on pages that exceed the page limitation will not be evaluated. Any content found in parts of the proposal for which there is no page limitations, where that content is not consistent with that part's intent (e.g., transmittal letter), will not be evaluated. The formatting instructions (character size and page size) are applicable to all pages of the technical proposal.

Notwithstanding any other provision or clause in this solicitation to the contrary, proposals shall be submitted via email to the Contract Specialist, Sean Gifford, at Gifford.Sean@epa.gov. **Offeror's responses submitted via any other means without prior written approval of the Contracting Officer WILL NOT be evaluated.**

VOLUME-SPECIFIC INSTRUCTIONS

(a) TECHNICAL PROPOSAL INSTRUCTIONS:

- (1) The technical proposal shall include the Offeror's responses to the evaluation factors listed in the "Task Order Technical Evaluation Factors", which are included in Attachment 2 to this solicitation. The technical proposal shall be organized in the same order as the evaluation factors presented in Attachment 2:

a. FACTOR 1: Technical Approach

This factor will evaluate the offeror's technical approach for the development and performance of all tasks requested in the PWS. The offeror shall demonstrate, at a minimum:

1. An understanding of the work to be performed;
2. The appropriate knowledge, capability (availability of appropriate staff, equipment, and resources), and ability to complete the tasks on time; and

3. An understanding of the typical problems encountered in performing services required within the PWS and the ability to present practical, efficient solutions for those problems.

The offeror's proposal shall include a clear, concise narrative that addresses each of the areas identified under the PWS.

b. FACTOR 2: Key Personnel

This criterion is established to evaluate the technical qualifications (experience, expertise and education) of the key personnel relative to the technical requirements of the PWS. The resume and information should clearly establish the individual's educational achievements and specific past experience as described in Attachment 2 - RFTOP Technical Evaluation Factors.

Note that individuals proposed as Key Personnel will be listed as such in the contract clause entitled "Key Personnel." Only one (1) individual may be proposed for each position.

For each key personnel, at a minimum, provide the individual's resume and present the following items in a simple, systematic table format or listing:

- A. Name, Professional Level, Job Title, and Proposed Role under the contract.
- B. Percent of time available for the contract and commitment letter if not already an employee of the prime or subcontractor.
- C. Degree(s) held and corresponding field of study.
- D. *Specific project experience related to the PWS area of responsibility.
- E. Job responsibility and goals met for project experience described in item D.
- F. Time dedicated to each project in item D.
- G. Beginning and ending dates of each project in item D.
- H. Current project commitments, including percent of time for each project, and duration of each project.

* It is not sufficient to merely state that an individual worked on a project. EXPLAIN WHAT HE/SHE DID AND ITS RELEVANCE TO THE REQUIREMENTS OUTLINED IN THE PWS.

c. FACTOR 3 – Past Performance

The offeror's proposal should describe the successful completion of contracts, subcontracts, and/or projects which are similar to the tasks requested in the Performance Work Statement within the past 5 years, or those that are currently ongoing. Offerors shall provide a brief description of each contract, subcontract,

and/or project which includes a description of objectives, the dollar value, relevance to the PWS, type of contract, the dates in which work was performed, and client contact information including name, address, point of contact, and telephone and/or email.

NOTE: You must notify all client contacts the government may be contacting them regarding your past performance of the projects in question.

Offerors shall provide the attached questionnaire to each of the client references and ask that they be provided to the Contract Specialist (CS) by the closing date of the RFTOP. If a questionnaire is not received by the closing of the RFTOP, the CS will make one additional attempt to receive a completed questionnaire from the client point of contact identified in the offeror's proposal. The EPA will consider this information, as well as information obtained from any other sources, when evaluating the past performance. Offerors may provide information on problems encountered on the identified contracts and the offeror's corrective actions taken. In the event where an offeror does not maintain a record of relevant past performance or for whom information on past performance is not available, the offeror may not be evaluated favorably or unfavorably on past performance and will receive a satisfactory rating "2" for the evaluation.

(2) Subcontractors

Each offeror shall list in a table format the name and addresses of all subcontractors who will perform work or labor or render services to the offeror for compensation in an amount in excess of one percent of the offeror's total price. Each offeror shall show on the table the portion of the work to be done by each subcontractor. This table shall be included with the technical proposal. The table shall include: (a) the name and address of the subcontractor, (b) a short description of the work the subcontractor will be designated to perform or deliver, (c) the portion in percent of the work (LOE) the subcontractor will be designated to perform or deliver.

(b) COST/PRICE PROPOSAL INSTRUCTIONS:

- i. Conflict of Interest:
Vendors shall provide a completed version of the certification in accordance with Local Clause EPA-H-09-106, Task Order Conflict of Interest Certification as part of its cost/price proposal.
- ii. The offeror's cost/price proposal shall be completely itemized by Task as outlined in the RFTOP Performance Work Statement. Each Task must be reflective of the line item type (Firm Fixed Price or Time & Materials) as indicated in each task.
- iii. The offeror shall identify the labor categories that may be utilized for work under the specific Tasks. Offerors shall provide the fully loaded labor rates which will apply during the Task Order Period of Performance. Proposed hourly rates shall not exceed that which is identified in the offeror's respective contract. For Time & Material Tasks, offerors shall sub-itemized both the fully burdened labor rates and any applicable materials.

- iv. The offeror shall not provide any proposed rates/pricing for Travel. Approval for contractor travel will be requested in accordance with Local Clause EPA-H-31-104, Approval of Contractor Travel.
- v. Proposals which include subcontracting shall also include the results of the prime contractor's evaluation of subcontract costs as required by FAR 15.404-3(b)(2).

NOTE 1: It is IMPORTANT that documentation be provided to support proposed rates for any direct labor, overhead, and/or general and administrative expense. Documentation may be in the form of payrolls, financial statements, and expense records. Detailed supporting computations must be provided in support of any proposed indirect rate(s). The computations may include historical, as well as budgeted, data. There must be an indication in the proposal as to whether the computations are based upon historical or projected data.

NOTE 2: If overhead and G&A rates proposed have been accepted on other Government contracts or have been approved in an audit by a Government agency, substantiating documentation of that acceptance or approval must be included with the proposal. That documentation shall include the names of agencies, contract numbers, contract titles, and/or the name and telephone number for the cognizant Government auditor.

References

Cornacoff, J.B., Graham, C.S., and LaBrie, T.K. 1995. Phenotypic identification of peripheral blood mononuclear leukocytes by flow cytometry as an adjunct to immunotoxicity evaluation. In *Methods in Immunotoxicology* (G.R. Burleson, J.H. Dean, and A.E. Munson, Eds.), Vol. 1, pp 211–226, Wiley-Liss, Inc., New York.

Cunningham, A.J. 1965. A method of increased sensitivity for detecting single antibody-forming cells. *Nature* 207:1106–1107.

Djeu, Julie Y. 1995. Natural Killer Activity. In *Methods in Immunotoxicology* (G.R. Burleson, J.H. Dean, and A.E. Munson, Eds.) pp 437–449.

Holsapple, M.P. 1995. The plaque-forming cell (PFC) response in Immunotoxicology: An approach to monitoring the primary effector function of B lymphocytes. In *Methods in Immunotoxicology* (G.R. Burleson, J.H. Dean, and A.E. Munson, Eds.), Vol. 1, pp. 71–108, Wiley-Liss, Inc., New York.

Ladies, G.S. and Loveless, S.E. 1994. Cell surface marker analysis of splenic lymphocyte populations of the CD rat for use in immunotoxicological studies. *Toxicol. Methods* 4: 77–91.

Ladies, G.S., Smith, C., Heaps, K., and Loveless, S.E. 1994. Evaluation of the humoral immune response of CD rats following a 2-week exposure to the pesticide carbaryl by the oral, dermal, or inhalation routes. *J. Toxicol. Environ. Health* 42:143–156.

Ladies, G.S., Smith, C., Heaps, K., Elliot, G.S., Slone, T.W., and Loveless, S.E. 1995. Possible incorporation of an immunotoxicological functional assay for assessing humoral immunity for hazard identification purposes in rats on standard toxicology study. *Toxicology* 96:225–238.

Luster, M.I., Portier, C., Pait, D.G., White, K.L., Jr., Gennings, C., Munson, A.E., and Rosenthal, G.J. 1992. Risk assessment in immunotoxicology I. Sensitivity and predictability of immune tests. *Fundam. Appl. Toxicol.* 18:200–210.

Luster, M.I., Portier, C., Pait, D.G., Rosenthal, G.J. Germolec, D.R., Corsini, E., Blaylock, B.L., Pollock, P., Kouchi, Y., Craig, W., White, D.L., Munson, A.E., and Comment, C.E. 1993. Risk Assessment in Immunotoxicology II. Relationships Between Immune and Host Resistance Tests. *Fundam. Appl. Toxicol.* 21:71–82.

Temple, L., T. T. Kawabata, A. E. Munson, and K. L. White, Jr. 1993. Comparison of ELISA and plaque-forming cell assays for measuring the humoral immune response to SRBC in rats and mice treated with benzo[a]pyrene or cyclophosphamide. *Fundam. Appl. Toxicol.* 21:412–419.

Temple, L., Butterworth, L., Kawabata, T.T., Munson, A.E., and White, K.L. 1995. ELISA to Measure SRBC Specific Serum IgM: Method and Data Evaluation. In *Methods in Immunotoxicology* (G.R. Burleson, J.H. Dean, and A.E. Munson, Eds.), Vol. 1, pp 137–157, Wiley-Liss, Inc.,

U.S. EPA Health Effects Test Guideline OPPTS 870.3100 90-Day Oral Toxicity in Rodents

U.S. EPA Health Effects Test Guideline OPPTS 870.7800 Immunotoxicity

Request for Task Order Proposal (RFTOP)

Attachment 2 – Technical Evaluation Factors

Laboratory Support for Repeated Dose Oral Toxicity Studies of Poly- and Perfluoroalkyl Substances in Rats

Offerors shall limit their responses to 25 pages or less, using their discretion on which criteria to place emphasis. If Key Personnel is identified as a criterion, resumes are limited to two pages or less and do not count towards the page limitation. The transmittal letter, cover pages, and dividers are also excluded from the page limitation. Any information on pages beyond the page number limitation will not be considered or evaluated. The technical proposal shall be submitted using no less than ten (10) point font size and no less than a 3/4" margin on all sides of the page. The term "Offeror" as used in this document shall mean the prime contractor and any proposed subcontractors or consultants.

Proposals will be evaluated on the evaluation factors listed below by the project Technical Evaluation Team and will be assigned a score from 0-3 using the scale listed below. Award will be based on Best-Value Analysis, where Technical Quality is more important than Cost/Price.

RATING SCALE

The following rating scale will be used in scoring proposals:

Unacceptable = 0. Evaluation factor is not addressed.

Poor = 1. The proposal fails to adequately address critical requirements of the PWS and technical evaluation factors; may satisfy some requirements, but not others; reflects major weaknesses or deficiencies. Could not meet requirements without fundamental changes involving a total re-write or redirection of the offer.

Satisfactory = 2. Proposal addresses and meets most requirements of the Task Order Performance Work Statement (PWS) and technical evaluation factors, with some correctable and minor weaknesses and/or deficiencies noted. Is generally considered to demonstrate at least minimum requisite experience, qualifications, and performance capabilities. Some discussions may be required to address and correct weaknesses or deficiencies.

Superior = 3. The proposal clearly addresses and exceeds requirements of the PWS and technical evaluation factors with no weaknesses or deficiencies, or very minor, correctable weaknesses or deficiencies noted.

Each point is worth 1/3 of the weight assigned to an individual evaluation factor.

EVALUATION FACTORS

The following evaluation factors and weights will be used in the technical evaluation of Task Order proposals:

FACTOR 1: Technical Approach – 50 points

This factor will evaluate the offeror's technical approach for the development and performance of all tasks requested in the PWS. The offeror shall demonstrate, at a minimum:

1. An understanding of the work to be performed;
2. The appropriate knowledge, capability (availability of appropriate staff, equipment, and resources), and ability to complete the tasks on time; and
3. An understanding of the typical problems encountered in performing services required within the PWS and the ability to present practical, efficient solutions for those problems.

The offeror's proposal shall include a clear, concise narrative that addresses each of the areas identified under the PWS.

FACTOR 2: Key Personnel – 30 points

This factor evaluates the technical qualifications (experience, expertise, and education) and availability of the proposed key personnel. The offeror's proposal should describe the technical qualifications (experience, expertise, and education) and availability, as it relates to the tasks set forth in the PWS, of the proposed Key Personnel. Minimum qualifications for each anticipated Key Personnel are as follows:

1. Lead Chemist – 12 points
 - a. Ph.D. chemistry with specialization in analytical chemistry. Experience in the use of chromatographic and mass spectral techniques for chemical analysis. Years of experience may replace degree level (M.S. – 4 years of experience; B.S. – 6 years of experience).
2. Lead Pathologist – 10 points
 - a. D.V.M. or Ph.D. in pathology, board certified pathologist with at least 2 years of experience.
3. Study Director – 8 points
 - a. Ph.D. in toxicology or related field with at least 2 years of experience in conducting guideline toxicology studies. Years of experience may be used in place of degree level (M.S. – 4 years of experience; B.S. – 6 years of experience).

Unless otherwise noted above, one individual should be proposed for each key personnel position identified above. The information provided by the offeror should clearly establish the individual's educational achievements, specific past experience in performing similar projects to those anticipated under the solicitation, including relevant publications, specific roles held by the proposed individual in projects cited, length of time he or she held those roles, goals met and achievements in the roles, and availability for effort on work anticipated herein, including commitment letters if not currently an employee of the prime or subcontractor. Note that individuals proposed as Key Personnel will be listed as such in the Task Order under clause

EPAAR 1552.237-72. At a minimum, provide the individual's resume (limited to 2 pages per individual) including the following items in a simple, systematic table format or listing:

- a. Name, Professional Level, Job Title, and Proposed Role under the contract.
- b. Percent of time available for the contract and commitment letter if not already an employee of the prime or subcontractor.
- c. Degree(s) held and corresponding field of study.
- d. Specific project experience related to the PWS area of responsibility. *
- e. Job responsibility and goals met for project experience described in item d.
- f. Time dedicated to each project in item d.
- g. Beginning and ending dates of each project in item d.
- h. Current project commitments, including percent of time for each project, and duration of each project.

* It is not sufficient to merely state that an individual worked on a project. EXPLAIN WHAT HE/SHE DID AND ITS RELEVANCE TO THE REQUIREMENTS OUTLINED IN THE PWS.

FACTOR 3: Past Performance – 20 points

The offeror's proposal should describe the successful completion of contracts, subcontracts, and/or projects which are similar to the tasks requested in the Performance Work Statement within the past 5 years, or those that are currently ongoing. Offerors shall provide a brief description of each contract, subcontract, and/or project which includes a description of objectives, the dollar value, relevance to the PWS, type of contract, the dates in which work was performed, and client contact information including name, address, point of contact, and telephone and/or email.

NOTE: You must notify all client contacts the government may be contacting them regarding your past performance of the projects in question.

Offerors shall provide the attached questionnaire to each of the client references and ask that they be provided to the Contract Specialist (CS) by the closing date of the RFTOP. If a questionnaire is not received by the closing of the RFTOP, the CS will make one additional attempt to receive a completed questionnaire from the client point of contact identified in the offeror's proposal. The EPA will consider this information, as well as information obtained from any other sources, when evaluating the past performance. Offerors may provide information on problems encountered on the identified contracts and the offeror's corrective actions taken. In the event where an offeror does not maintain a record of relevant past performance or for whom information on past performance is not available, the offeror may not be evaluated favorably or unfavorably on past performance and will receive a satisfactory rating "2" for the evaluation.

Attachment 3 - Past Performance Questionnaire

Offeror shall fill out top portion and send to Reference Organizations:

Name of Offeror Proposing on EPA Requirement: _____

Brief Description of this Project and Relevance to the EPA Project: _____

Name of Reference's Organization: _____

Contract Title: _____

Contract Number: _____ Contract Value: _____

Type of Contract: _____ Period of Performance: _____

The ratings indicated below are to be supplied by the reference identified above and not the offeror.

<u>Performance Elements</u>	<u>Outstanding</u> <small>(See Question 4)</small>	<u>Good</u>	<u>Acceptable</u>	<u>Marginal</u>	<u>Unsatisfactory</u> <small>(See Question 5)</small>
1. Technical Capability					
2. Project Schedule					
3. Project Management					

** Management, including subcontracts; reasonable/cooperative behavior; responsive to contract requirements; notification of problems; flexibility; proactive versus reactive.*

4. Remarks on Exceptional Performance:
(Provide data supporting this observation. You may continue on a separate sheet, if needed.)

5. Remarks on Unsatisfactory Performance:
(Provide data supporting this observation. You may continue on a separate sheet, if needed.)

6. Other Comments:
(You may continue on a separate sheet if needed.)

Attachment 6 – Past Performance Questionnaire (cont.)

7. Please identify any corporate affiliations with the offeror, if any.

8. Questionnaire completed by:

Name of Evaluator _____

Title _____

Date _____

Address _____

Phone number _____

Email: _____

Is the information presented at the top of form accurate: _____ YES _____ NO*

*If No, please describe the necessary corrections: _____

ATTACHMENT 4

QUALITY ASSURANCE SURVEILLANCE PLAN
FOR
TASK ORDERS

QUALITY ASSURANCE SURVEILLANCE PLAN

PERFORMANCE REQUIREMENT	PERFORMANCE MEASURE (PM)	PERFORMANCE STANDARD	SURVEILLANCE METHOD	INCENTIVES & DISINCENTIVES
<p><u>MANAGEMENT AND COMMUNICATION:</u></p> <p>The contractor shall maintain contact with the EPA Contracting Officer (CO), Contracting Officer Representative (COR), and Task Order Contracting Officer Representative (TOCOR) throughout the performance of the contract.</p>	<p>Contractor shall immediately bring potential problems to the appropriate EPA personnel and shall recommend actions that would mitigate or resolve the problem.</p>	<p>Issues that impact project schedules and costs shall be brought to the attention of the EPA within 3- business days of occurrence.</p>	<p>All active task orders will be reviewed by the EPA to identify unreported issues.</p>	<p>Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation of Business Relations in the Contractor Performance Assessment Reporting System (CPARS).</p>
<p><u>TIMELINESS:</u></p> <p>For every Task Order awarded establishing a firm, specific delivery date for the generation of a report, the contractor shall deliver such report to the COR, TOCOR and CO no later than the time specified in the order's PWS.</p>	<p>Deliverables and related work must comply with contractual timeliness requirements. The contractor will be evaluated on its responsiveness to all task orders.</p>	<p>95% of all deliverables and related work shall be completed on time within task schedule and/or tech. direction requirements.</p>	<p>100% inspection of all deliverables and related work by the TOCOR; TOCOR will document the timeliness of all work requirements.</p>	<p>Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation of Timeliness in the Contractor Performance Assessment Reporting System (CPARS).</p>
<p><u>TECHNICAL QUALITY:</u></p> <p>For every task order awarded, the analyses conducted by the contractor shall be factual, defensible, credible, and based on sound scientific methods. All data shall be collected from reputable sources and quality assurance measures shall be conducted in accordance with the agency requirements outlined in the task orders.</p>	<p>All deliverables and related work must be complete, accurate, thorough, and professionally credible.</p>	<p>Data are 100% accurate; review demonstrates a high level of expertise and credibility with regard to personnel and use of scientific methodology. Task Orders shall be conducted in strict conformance with approved QA plans. Outputs shall withstand internal review by the US EPA and outside scientific reviewers.</p>	<p>EPA Staff will conduct secondary reviews of work completed by the contractor. Feedback will be provided.</p>	<p>Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation in the category of Quality of Product or Service in the Contractor Performance Assessment Reporting System (CPARS).</p>